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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,152	02/26/1999	KENICHI HIGASHIYAMA	001560-344	6530

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RONALD L GRUDZIECKI
BURNS DOANE SWECKER & MATHIS
PO BOX 1404
ALEXANDRIA, VA 223131404

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/254,152	HIGASHIYAMA ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-73,75,-77, 86-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *76 and 77* is/are allowed.

6)☒ Claim(s) *70-73,75,86-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted September 23, 2004 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 70-73,75, 86-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended are directed to an edible-oil composition with specific limitations: an arachidonic acid content of 30-50%, a 24, 25-methylenecholest-5-en-3b-ol composition ratio in a proportion of 0.36 or less and/or a 24, 25-methylenecholest-5-en-3b-ol composition ratio of 0.24 or less. The specification does not provide sufficient written description as to the particular scope herein claimed. Among the four examples given in the application only one of them, example 4, meet the up boundary limitations. The application provide no further guidance, direction as to how to reduce the 24, 25-methylenecholest-5-en-3b-ol composition ratio while maintaining the high percentage of arachidonic acid.

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 70, 71, and 73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 4 of U.S. Patent No. 6,117,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matters in '905 is essentially the same as claimed herein, except claims of '905 have a narrower scope with respect to the amount of 24, 25-methylenecholest-5-en-3b-ol, and have broad scope with respect to the amount of arachidonic acid (30-50% herein vs. more than 20% in '905). Note the 24, 25-methylenecholest-5-en-3b-ol compositional ratio therein is less than 30% (0.15% of 24, 25-methylenecholest-5-en-3b-ol vs 0.6% of total unsaponifiable).

Claim Rejection 35 USC - 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 70-71, and 73 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shinmen et al. and Shimizu et al.

3. Shinmen et al. teach a process for production of an unsaturated fatty acid-containing oil comprising culturing with aeration a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a liquid medium containing a nitrogen source and collecting the unsaturated fatty acid-containing oil from the cultured product. See, particularly, the summary on page 11 and page 15, the left column. The nitrogen source can be a defatted soybean product, e.g., soybean meal. See, particularly, page 14, left column, the second paragraph. The unsaturated fatty acid-containing oil contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen et al. do not disclose 24,25-methylenecholest-5-en-3b-ol compositional ratio or the proportion of 24,25-methylenecholest-5-en-3β-ol, or compositional ratio with respect to desmosterol composition ratio. However, Shimizu et al. teach that an unsaturated fatty acid-containing oil obtained from a process similar to the process of Shinmen et al. has a 24,25-methylenecholest-5-en-3β-ol compositional ratio of 21 % and 24,25-methylenecholest-5-en-3β-ol compositional ratio in a proportion of 0.37 with respect to desmosterol composition ratio. See, page 482, table 1. Therefore, properties such as having a 24,25-methylenecholest-5-en-3β-ol compositional ratio of 24 % or less and 24,25-methylenecholest-5-en-3β-ol compositional ratio in a proportion of 0.36 or less with respect to desmosterol composition ratio are considered inherent properties of the unsaturated fatty acid-containing oil of Shinmen et al. As to the method of making the product, note, [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made

by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Absent evidence showing the differences, the claimed invention is anticipated by Shinmen et al.

Claim Rejection 35 USC – 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 70-73, 75, 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmen et al in view of both of Shimizu et al and Barclay.

Shinmen et al. teach a process for production of an unsaturated fatty acid-containing oil comprising culturing with aeration a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a liquid medium containing a nitrogen source and collecting the unsaturated fatty acid-containing oil from the cultured product. See, particularly, the summary on page 11 and page 15, the left column. The nitrogen source can be a defatted soybean product, e.g., soybean meal. See, particularly, page 14, left column, the second paragraph. The unsaturated fatty acid-containing oil contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen et al. do not disclose 24,25-methylenecholest-5-en-3b-ol compositional ratio or the proportion of 24,25-methylenecholest-5-en-3β-ol, or compositional ratio with respect to desmosterol composition ratio. However, Shimizu et al. teach that an unsaturated fatty acid-containing oil obtained from a process similar to the process of Shinmen et al. has a 24,25-methylenecholest-5-en-3β-ol compositional ratio of 21 % and 24,25-methylenecholest-5-en-3β-ol compositional ratio in a proportion of 0.37 with respect to

desmosterol composition ratio. See, page 482, table 1. Therefore, properties such as having a 24,25-methylenecholest-5-en-3β-ol compositional ratio of 35 % or less and 24,25-methylenecholest-5-en-3β-ol compositional ratio in a proportion of 1.2 or less with respect to desmosterol composition ratio are considered inherent properties of the unsaturated fatty acid-containing oil of Shinmen et al. Further, Shinmen also teach the nutritive effect of arachidonic acid. See, particularly, the introduction on page 11.

Shinmen et al. does not teach expressly the employment of such oil in food products including baby food and animal food.

However, Barclay teaches the employment of arachidonic acid containing oil obtained from culturing microorganism Mortierella for food product including baby food and animal food. See, particularly, column 7, line 48-60.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the oil obtained from the microorganism, as exemplified by Shinmen, in food product including baby food and animal food.

4. A person of ordinary skill in the art would have been motivated to employ the oil food product including baby food and animal food because the arachidonic acid containing oil is known to be useful in food product including baby food and animal food. As to the method of making the product, note, [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to the Arguments

Applicants' amendments and remarks submitted September 23, 2004 have been fully considered.

The arguments regarding claims 76 and 77 are persuasive. Particularly, even though the cited references suggest the usefulness of soybean product as nitrogen source, there is no teaching or suggestion that the employment of soybean product for the particular microorganism herein would yield unexpected low content of 24, 25-methylenecholest-5-en-3b-ol.
The amendments and argument s are persuasive to over come the rejections under 35 U.S.C. 102

The arguments regarding the rejections set forth above are found not persuasive.

5. As to the double patenting rejections, applicants argue that claims in '905 and herein are distinct because instant claims are characterized by the ratio of 24, 25-methylenecholest-5-en-3β-ol, and claims in '905 are characterized by the absolute content of 24, 25-methylenecholest-5-en-3β-ol. The arguments are not persuasive. Particularly, '905 effectively claims the ratio herein claimed. Note the 24, 25-methylenecholest-5-en-3b-ol compositional ratio therein is less than 30% (0.15% of 24, 25-methylenecholest-5-en-3b-ol vs 0.6% of total unsaponifiable), meet the limitation. Therefore, the claims herein are generic to claims in '905. '905 further require a limitation of absolute content, which do not required herein. As to the method of making the product, note, [E]van though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

As to the rejections under 35 U.S.C. 102 and 103, note as shown by Shimizu that arachidonic acid composition produced by the microorganism herein generally containing 24, 25-methylenecholest-5-en-3β-ol in a ratio close to the claimed limitation. It would have been reasonably expected that the compositions produced by Shinmen et al. would have 24, 25-methylenecholest-5-en-3b-ol in a ratio within the claimed limitation. It is applicants burden to show that the subject matter shown to be in the prior art does not posses the characteristic relied on in the instant claims.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617